

REMARKS

A. Regarding the Amendments

By the present amendment, claims 82 and 83 have been canceled without prejudice. Claims 76 and 77 have been amended to perfect the dependency. No new matter has been added. The Applicant acknowledges the withdrawal of the previous rejections of claims 67, 70, 73, and 75, under 35 U.S.C. § 112, first paragraph (enablement), and of claims 67 and 70, under 35 U.S.C. § 112, second paragraph, in view of the arguments made by the Applicant, as well as the withdrawal of the previous rejection of claims 67, 70 and 73-91 under the non-statutory, judicially created doctrine of obviousness-type double patenting.

With regard to claims 80 and 88-91 that were rejected under 35 U.S.C. § 112, first paragraph (enablement) in the previous Office Action mailed June 10, 2005, the Applicant has also noted that in the present Office Action the Examiner did not state that the rejection of claims 80 and 88-91 has been withdrawn (see, page 2 of the Office Action, last paragraph). At the same time, the Examiner has not indicated that the rejection of claims 80 and 88-91 has been maintained (see, page 2 of the Office Action, last line). Accordingly, the Applicant respectfully assumes that the previous rejection of claims 80 and 88-91 no longer applies.

Upon entry of this amendment, claims 67, 70, 73-81, 84-91, and 95 will be under consideration.

B. Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 74, 76-79, 82 and 83 have been rejected under 35 U.S.C. § 112, first paragraph (page 2, last line through page 3, line 2 of the Office Action). This rejection is respectfully traversed on the following grounds.

It is respectfully submitted that in this case the Examiner has not met the burden of demonstrating the alleged lack of enablement under the standard established by *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993), as discussed in the response filed on August 10, 2005. Claims 82 and 83 have been canceled, and therefore the rejection is moot with respect to these claims. With respect to claims 74, 76-79, the Applicant submits that the specification does comply with the enablement requirement since no undue experimentation is needed to practice the methods recited in claims 74, 76-79.

Specifically, claims 74 and 76-79 are directed to the methods for treatment of certain mitochondrial disorders, wherein the disorder is caused by various causes listed in these claims. It is submitted that, the specification discloses the compounds to be used, the dosage (page 12, lines 6-13), the duration of treatment (examples 1-5), and other conditions for treatment (pages 10-11). Thus, it is submitted that the application provides clear directions for practicing the invention. No more is required to enable claims 74 and 76-79.

In the enablement context, the course of treatment that is discussed above applies to all the disclosed and discussed disorders, regardless of the cause of the disorder, because ways of practicing the invention do not change depending on the cause of the disorder. Thus, once the application provides directions on how to use the drug or formula (I) as shown in claim 67, the enablement test is met.

The Examiner has mentioned that the specification “is silent concerning the administration of drugs for the treatment … a deficiency of cardiolipin” (page 3, lines 1-2 of the Office Action). Logically, it appears that the grounds for the Examiner’s rejection is the rejection due to the lack of written description rather than rejection due to the lack of enablement.

However, the Examiner had previously withdrawn the rejection due to the lack of written description (see, the Office Action dated June 10, 2005, at page 2). In addition,

with regard to claim 74, cardiolipin (diphosphatidyl glycerol) is well known as an insulator that can stabilize the activity of protein complexes important to the electron transport chain. The specification discloses that the disorders discussed therein may affect “the transport of macromolecules into or out of mitochondria” (see, page 1, line 20 of the specification). Taking this disclosure together with the known properties of cardiolipin, it is submitted that the specification inherently teaches that one condition causing the mitochondrial disorder can be a deficiency of cardiolipin.

The Examiner has also alleged that the specification “is silent concerning the administration of drugs for the treatment of … lower than normal uridine levels” (page 3, lines 1-2 of the Office Action), as recited in claim 79. The Applicant respectfully disagrees. The specification states that the methods of the invention are “are contemplated for use in the treatment of all mitochondrial disorders, … most particularly those associated with a deficiency in uridine” (page 7, lines 1-3). Clearly, the expression “associated with a deficiency in uridine” and “resulting in lower than normal uridine levels” are synonymous because the plain meaning of the word “deficiency” is “lower or less than normal or usual.” Accordingly, it is submitted that the rejection does not apply to claim 79.

In view of the foregoing, the Applicant respectfully submits that the rejection of claims 74, and 76-79 under 35 U.S.C. § 112, first paragraph, has not been properly applied. Reconsideration and withdrawal of the rejection are respectfully requested.

C. Rejection Under 35 U.S.C. § 103 (a)

Claims 67, 70 and 73-91 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Page et al., “Developmental Disorder Associated with Increased Cellular Nucleotidase Activity,” *Proc. Natl. Acad. Sci. USA*, vol. 94, pp. 11601-11606 (1997) in view of U.S. Patent No. 6,472,378 to von Borstel (page 3, lines 15-17 of the Office Action). This rejection is respectfully traversed.

It is settled law that to establish a *prima facie* case of obviousness, the following three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference as proposed by the Examiner; (2) there must be a reasonable expectation of success and (3) the prior art reference must teach or suggest all of the claim limitations. MPEP § 2143.

It is also well established that a 35 U.S.C. § 103 rejection must be based on a sub-section of 35 U.S.C. § 102. See, MPEP § 2141.01. In other words, to qualify as a valid 35 U.S.C. § 103 reference, the reference must also qualify as prior art under a section of 35 U.S.C. § 102. See, *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597 (Fed. Cir. 1987). Applicants submit that the above criteria have not been met.

Specifically, Page et al. disclose treatment of various developmental disorders, but fails to disclose or suggest treatment of mitochondrial disorders recited in claims 67 and 91. To cure this deficiency of Page et al., the Examiner has proposed to combine the teachings of Page et al. with the teachings of von Borstel. However, von Borstel does not qualify as prior art under any sub-section of 35 U.S.C. § 102.

The Applicant respectfully reminds that on March 3, 2005, the Applicant executed a Declaration under 37 C.F.R. § 1.131. The Declaration was filed on March 9, 2005, together with the response to the Office Action dated September 9, 2004. In the Office Action that followed, dated June 6, 2005, the Examiner agreed that the Declaration properly antedates the very same von Borstel reference (see, the Office Action dated June 6, 2005, page 2, line 20 through page 3, line 4). Accordingly, it is submitted that von Borstel is not a proper 103 reference and cannot be used to cure the deficiencies of Page et al.

In view of the foregoing, it is respectfully submitted that each of claims 67 and 91 is patentably distinguishable over Page et al. in view of von Borstel. Each of claims 70

In the Application of
Robert K. Naviaux
Application Serial No.: 09/889,251
Filed: November 1, 2001
Page 10

PATENT
Attorney Docket No.: UCSD1140-1

and 73-90 depends, directly or indirectly, on claim 67, and is allowable for at least the same reason. Reconsideration and withdrawal of the rejection are respectfully requested.

In the Application of
Robert K. Naviaux
Application Serial No.: 09/889,251
Filed: November 1, 2001
Page 11

PATENT
Attorney Docket No.: UCSD1140-1

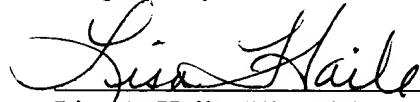
CONCLUSION

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved, the Examiner is requested to contact the undersigned at the telephone number given below so that a prompt disposition of this application can be achieved.

No fee is believed due in connection with this Response. In the event that an additional fee is due, the Commissioner is hereby authorized to charge any amounts required by this filing, or credit any overpayment, to Deposit Account No. 07-1896.

Respectfully submitted,

Date: December 12, 2005



Lisa A. Haile
Lisa A. Haile, J.D., Ph.D.
Registration No. 38,347
Telephone: (858) 677-1456
Facsimile: (858) 677-1465

DLA PIPER RUDNICK GRAY CARY US LLP
4365 Executive Drive, Suite 1100
San Diego, California 92121-2133
USPTO Customer Number 28213